Remarks

The various parts of the Office Action (and other matters, if any) are discussed below under appropriate headings.

Specification

The Examiner has suggested the addition of headings to the various sections of the specification. By way of the foregoing amendments to the specification, this suggestion has been adopted.

Claim Rejections - 35 USC § 101

Claims 11, 12, 20 and 21 stand rejected as being directed to non-statutory subject matter. By way of the foregoing amendments, claims 11 and 20 have been amended to remove any issue as to non-statutory subject matter. Claims 12 and 21 have been canceled and, thus, the rejection of these claims is moot.

Claim Rejections - 35 USC § 112

Claims 9 and 10 stand rejected as being indefinite due to lack of antecedent basis of certain terms. By way of the foregoing amendments, claims 9 and 10 have been amended to remove any issue as to the lack of antecedent basis and, therefore, the rejection is moot.

Claim Rejections - 35 USC § 102 and § 103

Claims 1-23 stand rejected as being anticipated by *Lemelson* (U.S. 5,919,135) and/or *Kucharczyk* (U.S. 6,026,316). Withdrawal of the rejection is respectfully requested for at least the following reasons.

Independent claims 1, 13 and 15 have been amended herein and now recite that prior to positioning an infusion or withdrawal catheter in a body of the patient, an infusion of a substance into the patient is planned, said plan including a simulation of the planned infusion.

For example, patient data, such as parameters related to tissue or body structure of the patient are collected. These parameters may include tissue density, distribution of particular tissue structures, or the blood flow through a particular area of tissue. Prior

to positioning an infusion or withdrawal catheter, a plan of the infusion is created so as to optimize delivery of the substance. The plan can be based on the patient data and other criteria. Further, the plan includes a simulation of the planned infusion.

Lemelson describes a system for treating cellular disorders in a living being. More specifically, *Lemelson* discloses that coordinates of select tissue, in which a catheter based operation is to be performed, are defined or computed with respect to images of the patient's anatomy.[1] *Lemelson* also discloses that an optimum dose can be calculated based on known fluid modeling techniques,[2] and that a dose of a particular drug may be adjusted after an initial dose has been administered.[3] In determining the optimum dose, *Lemelson* discloses several methods for collecting data for use in the model, wherein each method requires inserting or advancing an infusion or withdrawal catheter into the patient.[4] Thus, *Lemelson* has not been found to teach or suggest that *prior to positioning an infusion or withdrawal catheter in a body of the patient, an infusion of a substance into the patient is planned, said plan including a simulation of the planned infusion*, as recited in claims 1, 13 and 15.

Kucharczyk describes a method for targeting drug delivery into a living patient using magnetic resonance (MR) imaging. Ths system monitors the spatial distribution kinetics of the injected or infused drug agent quantitatively and non-invasively using water proton directional diffusion MR imaging to establish the efficacy of drug delivery at a targeted location.[5] In other words, *Kucharczyk* discloses a method wherein drug delivery is monitored **as it is being administered** and/or **after it has been administered** to the patient. This is further evident in Fig. 7 of *Kucharczyk* (cited by the Examiner), which is titled "Flowchart for MRI Tracking Drug Delivery". The title itself implies the drug dispersion is tracked via MR scans *as or after the drug is delivered*, and not planned in advance to delivery. Moreover, Fig. 7 clearly shows that MR images are obtained over time (fifth block from bottom) and, due to the presence of the drug, those images will change in contrast (fourth block from bottom). The acquired images then are compared to an initial image to determine the efficacy of the delivery. No

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[1] Column 4, lines 5-8 of *Lemelson*

[2] Column 13, lines 26-30 of *Lemelson*

[3] Column 13, lines 59-67 of *Lemelson*

[4] Column 12, line 37-column 13, line25 of *Lemelson*

[5] Abstract of *Kucharczyk*

mention is made in Fig. 7, however, of a plan of the drug delivery. *Kucharczyk* also has not been found to teach or suggest that *prior to positioning an infusion or withdrawal catheter in a body of the patient, an infusion of a substance into the patient is planned, said plan including a simulation of the planned infusion*, as recited in claims 1, 13 and 15.

Claims 2-11, 14 and 16-20 depend from one of the above independent claims and, therefore, can be distinguished from the cited art for at least the same reasons.

Accordingly, withdrawal of the rejection of claims 1-21 is respectfully requested.

B. Claims 22-23

Independent claim 22 recites a device for carrying out an infusion, wherein the device includes a verification device for comparing planned infusion data with actual infusion data.

The Examiner cites to Fig. 7 of *Kucharczyk* as teaching the features of claim 22. Fig. 7, however, does not teach or suggest a planned infusion. Instead, Fig. 7 simply provides the steps for obtaining MR images, delivery of the drug to the patient, obtaining images of the patient ***as or after*** the drug is delivered, and then superimposing the drug delivery map on an anatomic map of target tissue (i.e., an initial MR image) to determine the efficacy of the drug delivery. The comparison of the final delivery map with the initial delivery map is simply a "before and after" comparison (i.e., the patient's MR scans before delivery with the patient's MR scans after delivery). No mention is found in Fig. 7 of ***planned*** infusion data, or comparing the planned infusion data with actual data, as recited in claim 22.

As noted above, *Lemelson* discloses that a dose of a particular drug may be adjusted after an initial dose has been administered. *Lemelson*, however, has not been found to teach or suggest a verification device for comparing *planned infusion data* with *actual infusion data*, as recited in claim 22.

Claim 23 depends from claim 22 and, therefore, can be distinguished from the cited art for at least the same reasons.

Accordingly, withdrawal of the rejection of claims 22 and 23 is respectfully requested.

Conclusion

In view of the foregoing, request is made for timely issuance of a notice of allowance.

Respectfully submitted,

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CERTIFICATE OF MAILING (37 CFR 1.8a)

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Christine Arndt

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